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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,423	12/01/2000	Michael Houghton	1618.003	3252

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/728,423

Applicant(s)

HOUGHTON ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1- 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1- 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

This action is in response to paper# 8.

Claims 1- 27 are under consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 27 is drawn to a further step in the method of claim 1 which is drawn to eliciting an immune response to HCV E2 or E1E2 that is not secreted by immunizing with *nucleic acid* coding for immunogen. Claim 27 adds a subsequent immunization (or boost) with the *protein* encoded by the polynucleotide of claim 1.

The specification does not convey that the use of a polypeptide boost was done. Pages 31- 41 discuss the immunizing with DNA or polypeptides but not the combination as claimed. The specification does not provide any examples that show that "boosting" with the polypeptide encoded by the polynucleotide used to inoculate the subject is

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better or produces unexpected results or is different than boosting with the polynucleotide, which is known in the art, see Forns below.

While an original claim may provide support, there is no written description in the specification that indicates that this was the way in which the method was reduced to practice.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 5, 10, 14, 15, and 17- 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishi.

Ishi discloses eliciting an immune response against an HCV E2 antigen a polynucleotide encoding E1E2 or full length E2 that is on the cell surface and is not secreted by means of HCV virions from transfusions or needle sticks and discloses NOB titers that meet the limitations of the claims (see Methods and Table 1).

Claims 1, 3, 5, 6, 8, 10, 12, and 14- 17 rejected under 35 U.S.C. 102(a) as being anticipated by Forns.

Forns discloses a polynucleotide that encodes a E2 protein with and without P7 that can be used for eliciting an immune response to HCV E2. Fornes also teaches delivery by microparticle, repeating the administration of polynucleotide encoding the protein, and that the polynucleotide is in a plasmid ( Figure 1, page 1995, Figure 3, Figure 4, and Table 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 9, 11, 13, and 18- 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fornes.

Fornes as discussed above teaches eliciting an immune response against a HCV E2 antigen by administering a polynucleotide encoding the antigen. The polynucleotides of Fornes, while not identical in length, contain the epitopes that give rise to NOB antibodies and thus would have similar function in the eliciting of antibodies in an immune response.

Fornes discloses that antibodies reactive to E2 were isolated (Table 1).

Knowing the construct of Fornes contains all of E2, one of skill in the art would know that it contains the epitopes that give rise to NOB antibodies and it would have been within the skill of one of ordinary skill in the art to assay the antibodies of Fornes for

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NOB antibodies such as with the method as disclosed in Ishi (*supra*, page 118, Column 1, last full paragraph).

The use of agents to prepare the site for DNA inoculations is known in the art, such as cardiotoxin (see Nielson, *AMPIS* 1998) as well as various methods to prepare DNA for inoculation, including different forms of microparticles and related preparations.

In the art of vaccination and immunization studies, boosting with antigen is known, as done in Forns, above.

Thus, it would have been *prima facie* obvious to detect the NOB antibodies in the method of Forns with the assay of Ishi or administer the polynucleotide in different formulations with the expectation of success.

### ***Conclusion***

No claim is allowed.

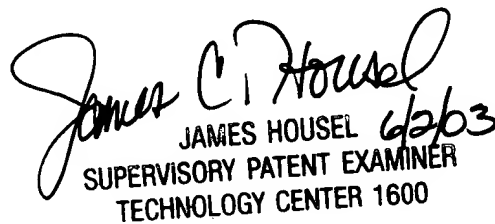
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill  
Patent Examiner  
May 23, 2003



JAMES HOUSEL 6/2/03  
SUPERVISORY PATENT EXAMINER  
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